FEB - 6 2004

K030685

1.5 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason, Sr. Regulatory Affairs Specialist
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Date of Submission:	March 3, 2003
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Teeth in an Hour - ARK Implant Concept
Legally Marketed Device(s):	Branemark Novum (K000018) Branemark System Implants – Immediate Function Indication (K022562)

Device Description:
The Teeth in and Hour – ARK Implant System is a concept bridging the use of existing modeling techniques to existing denture technology through a surgical template that transfers pre-determined implant locations to a patient.

Existing modeling techniques are performed to create a model of a patient's jaw in order to pre-determine implant location. A surgical template, comprised of acrylic material with cylinders and sleeves embedded, and based upon the modeling, is produced for the purpose of transferring the pre-determined implant locations to the patient. During surgery, the surgical template is held in position in the patient's mouth using anchor pins, which are removed after surgery. Osteotomies are created using the surgical template, necessary drills, and accessories. Implants are then placed into the jaw using standard technique. The surgical template and anchor pins are then removed. After the implants are inserted, this concept then allows for pre-produced prosthetic reconstruction to be attached.

Indications for Use:
The Teeth in an Hour - ARK Implant Concept is indicated for the treatment of totally or partially edentulous patients for placement of two or more implant fixtures with immediate load function to restore the patient's chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 - 2004

Nobel Biocare AB
C/O Ms. Elizabeth J. Mason
Senior Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway,
Yorba Linda, California 92887

Re: K030685
Trade/Device Name: Teeth in an Hour-ARK Implant Concept
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: November 11, 2003
Received: November 12, 2003

Dear Ms. Mason:

This letter corrects our substantially equivalent letter of November 11, 2003 regarding the Device Name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

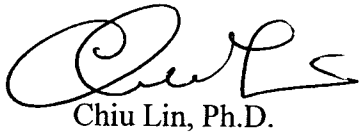
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030685

Device Name: Teeth in an Hour - ARK Implant Concept

Indications For Use:

The Teeth in an Hour - ARK Implant System is indicated for the treatment of totally edentulous jaws for placement of implant fixtures with immediate load function to restore the patient's chewing function. The following prerequisites must be fulfilled:

* adequate amount of jaw bone
* the quality of jaw bone must be judged as adequate
* capability to open the mouth at least 50mm (this is especially important for lower jaws with teeth in the opposite jaw)

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030685